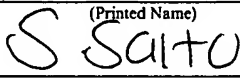




Atty. Dkt. No. 060925-0601

THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicant: H. Michael SHEPARD
Title: METHODS FOR TREATING
THERAPY-RESISTANT
TUMORS
Appl. No.: 10/048033
International Filing Date: 7/21/2000
371(c) Date:

CERTIFICATE OF EXPRESS MAILING	
I hereby certify that this correspondence is being deposited with the United States Postal Service's "Express Mail Post Office To Addressee" service under 37 C.F.R. § 1.10 on the date indicated below and is addressed to: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.	
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Susana Salto (Printed Name)	
 (Signature)	

Examiner: Crane, Lawrence E.
Art Unit: 1623
Confirmation Number: 2767

SUPPLEMENTAL INFORMATION DISCLOSURE STATEMENT
UNDER 37 CFR §1.56

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Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Sir:

Submitted herewith on Form PTO/SB/08 is a listing of documents known to Applicants in order to comply with Applicants' duty of disclosure pursuant to 37 CFR §1.56.

A copy of each non-U.S. patent document and each non-patent document is being submitted to comply with the provisions of 37 CFR §1.97 and §1.98.

The submission of any document herewith, which is not a statutory bar, is not intended as an admission that such document constitutes prior art against the claims of the present application or that such document is considered material to patentability as defined in 37 CFR

§1.56(b). Applicants do not waive any rights to take any action which would be appropriate to antedate or otherwise remove as a competent reference any document which is determined to be a *prima facie* art reference against the claims of the present application.

TIMING OF THE DISCLOSURE

The listed documents are being submitted in compliance with 37 CFR §1.97(b), before the mailing date of the first Office Action on the merits.

RELEVANCE OF EACH DOCUMENT

All of the documents are in English.

Applicants respectfully request that each listed document be considered by the Examiner and be made of record in the present application and that an initialed copy of Form PTO/SB/08 be returned in accordance with MPEP §609.

Although Applicant believes that no fee is required for this Request, the Commissioner is hereby authorized to charge any additional fees which may be required for this Request to Deposit Account No. 50-0872.

Respectfully submitted,

Date January 11, 2007

FOLEY & LARDNER LLP
Customer Number: 38706
Telephone: (650) 251-1129
Facsimile: (650) 856-3710

By Antoinette F. Konski

Antoinette F. Konski
Attorney for Applicant
Registration No. 34,202

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Substitution for form 1449/PTO INFORMATION DISCLOSURE STATEMENT BY APPLICANT Date Submitted: January 10, 2007 (use as many sheets as necessary)				Complete if Known	
Application Number				10/048033	
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First Named Inventor				H. Michael Shepard	
Art Unit				1623	
Examiner Name				Crane, Lawrence E.	
Attorney Docket Number				060925-0601	

[illegible]

UNPUBLISHED U.S. PATENT APPLICATION DOCUMENTS					
Examiner Initials*	Cite No. ¹	U.S. Patent Application Document	Filing Date of Cited Document MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear
		Serial Number-Kind Code ² (if known)			

FOREIGN PATENT DOCUMENTS						
Examiner Initials*	Cite No. ¹	Foreign Patent Document	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Documents	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear	T ⁶
		Country Code ³ Number ⁴ Kind Code ⁵ (if known)				
	7	EP 0095294	11-30-1983	Beecham Group PLC		
	8	EP 0283065	09-21-1988	Stichting REGA VZW		
	9	WO 92/020344	11-26-1992	Glaxo Group Ltd.		
	10	WO 95/09865	04-13-1995	Terrapin Technologies, Inc.		

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Sheet	2	of	6	Attorney Docket Number	060925-0601

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	11	WO 99/08110	02-18-1999	NewBiotics, Inc.		

NON PATENT LITERATURE DOCUMENTS			
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	12	ALMASAN et al. "Deficiency of retinoblastoma protein leads to inappropriate S-phase entry, activation of E2F-responsive genes, and apoptosis" PNAS, USA 92:5436-5440 (June 1995)	
	13	ASCHELE et al. (June 1999) "Immunohistochemical quantitation of thymidylate synthase expression in colorectal cancer metastases predicts for clinical outcome to fluorouracil-based chemotherapy" J. Clin. Oncol. 17(6):1760-1770	
	14	BALZARINI et al., "Increased sensitivity of thymidine kinase-deficient (TK-) tumor cell lines to the cell growth inhibitory effects of (E)-5-(2-bromovinyl)-2'-deoxyuridine (BVDU) and related compounds", Anticancer Research, vol. 6, 1986, pp. 1077-1084, Belgium, 1986.	
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	17	BASTIAN et al. "Inhibition of thymidylate synthetase in thymidylate synthase" J. Med. Chem. 24:1385-1388 (1981)	
	18	CRUICKSHANK et al. "Oligonucleotide labeling: A concise synthesis of a modified thymidine phosphoramidite" Tetrahedron Lett. 29(41):5221-5224 (1988)	
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	20	DOLNICK et al. "rTS Gene Expression is Associated with Altered Cell Sensitivity to Thymidylate Synthase Inhibitors" Adv. Enzyme Reg. (1996) 36:165-180	

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		First Named Inventor	H. Michael Shepard
		Art Unit	1623
		Examiner Name	Crane, Lawrence E.
Sheet 3 of 6	Attorney Docket Number	060925-0601	

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	21	EDLER et al. "Immunohistochemically detected thymidylate synthase in colorectal cancer: An independent prognostic factor of survival" <i>Clinical Cancer Research</i> 6:488-492 (February 2000)	
	22	FAN et al. "Functional roles of E2F in cell cycle regulation" <i>Oncogene</i> 14:1191-1200 (1997)	
	23	FREEMANTLE et al. "Molecular characterisation of two cell lines selected for resistance to the folate-based thymidylate synthase inhibitor, ZD1694" <i>British Journal of Cancer</i> 71:925-930 (1995)	
	24	FUNK "Cancer cell cycle control" <i>Anticancer Research</i> 19:4772-4780 (1999)	
	25	GOEL et al. "Selective Intraperitoneal Biochemical Modulation of Methotrexate by Dipyrindamole" <i>J. Clin. Oncol.</i> (February 1989) 7(2):262-269	
	26	GORLICK et al. "Drug Resistance in Colon Cancer" <i>Semin. Oncol.</i> (December 1999) 26(6):606-611	
	27	GRIFFITH et al. "Differential Inhibition of Nucleoside Transport Systems in Mammalian Cells by a New Series of Compounds Related to Lidoflazine and Mioflazine" <i>Biochem. Pharmacol.</i> (1990) 40(10):2297-2303	
	28	HOWELL et al. "Comparison of the Synergistic Potentiation of Etoposide, Doxorubicin, and Vinblastine Cytotoxicity by Dipyrindamole" <i>Cancer Res.</i> (June 15, 1989) 49:3178-3183	
	29	HUSAIN et al. "Elevation of topoisomerase I messenger RNA, protein, and catalytic activity in human tumors: Demonstration of tumor-type specificity and implications for cancer chemotherapy" <i>Cancer Research</i> 54:539-546 (January 15, 1994)	
	30	JACKMAN "Folate-based thymidylate synthase inhibitors as anticancer drugs" <i>Ann. Oncol.</i> 6(9):871-881 (1995)	
	31	JONES and MANN "New methods of synthesis of β -aminoethylpyrazoles" <i>J. Am. Cancer Soc.</i> 75: 4048-4052 (1953)	
	32	KRAJEWSKA et al. "Pyrimidine ribonucleoside phosphorylase activity VS 5- and/or 6-substituted uracil and uridine analogues, including conformational aspects" <i>Biochem. Pharmacol.</i> 31(6):1097-1102 (1982)	

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Sheet	4	of	6
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	33	KRAUPP et al. "Membrane Transport of Nucleobases: Interaction with Inhibitors" <i>Gen. Pharmacol.</i> (1995) 26(6):1185-1190	
	34	LACKEY et al. "Enzyme-catalyzed therapeutic agent (ECTA) design: activation of the antitumor ECTA compound NB1011 by thymidylate synthase" <i>Biochem. Pharmacol.</i> (2001) 61:179-189	
	35	LEE et al. "Inhibition of mouse thymidylate synthase promoter activity by the wild-type p53 tumor suppressor protein" <i>Exp. Cell Res.</i> 234:270-276 (1997)	
	36	LENZ et al. "p53 and thymidylate synthase expression in untreated stage II colon cancer: associations with recurrence, survival, and site" <i>Clinical Cancer Research</i> 4:1227-1234 (May 1998)	
	37	LEHMAN et al. "Modulation of RTX cytotoxicity by thymidine and dipyridamole in vitro: implications for chemotherapy" <i>Cancer Chemother. Pharmacol.</i> (2000) 45:142-148	
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	39	LENZ et al. "Thymidylate Synthase mRNA Level in Adenocarcinoma of the Stomach: A Predictor for Primary Tumor Response and Overall Survival" <i>J. Clin. Oncol.</i> (1995) 14(1):176-182	
	40	LEŠ et al. "Modeling of reaction steps relevant to deoxyuridylate (dUMP) enzymatic methylation and thymidylate synthase mechanism-based inhibition" <i>Journal of Biomolecular Structure & Dynamics</i> 15(4):703-715 (1998)	
	41	LOOK et al. "Increased thymidine kinase and thymidylate synthase activities in human epithelial ovarian carcinoma" <i>Anticancer Res.</i> 17:2353-2356 (1997)	
	42	MADEC et al. "Some characteristics of fetal and adult isoenzymes of thymidine kinase in human breast cancers" <i>Bull. Cancer</i> 75:187-194 (1998)	
	43	MADER et al. "Resistance to 5-fluorouracil" <i>Gen. Pharma.</i> 31(5):661-666 (1998)	

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	44	MAHONY et al. "Dipyridamole Kinetics" <i>Clin. Pharmacol. Ther.</i> (March 1982) 31(3) :330-338	
	45	MOBASHERY et al. "Conscripting β -lactamase for use in drug delivery. Synthesis and biological activity of a cephalosporin C10-ester of an antibiotic dipeptide" <i>J. Am. Chem. Soc.</i> 108:1686-1688 (1986)	
	46	NEGISHI et al. "Enhancement of N4-aminocytidine-induced mutagenesis by Ni ⁺⁺ ion" <i>Nucl. Acids Symposium</i> 35:137-138 (1996)	
	47	NELSON et al. "Potentiation of Methotrexate Toxicity by Dipyridamole" <i>Cancer Res.</i> (June 1984) 44 :2493-2496	
	48	PARADISO et al. "Thymidilate synthase and p53 primary tumour expression as predictive factors for advanced colorectal cancer patients" <i>British J. of Cancer</i> 82(3):560-567 (2000)	
	49	PEGGRAM et al. "The effect of HER-2/neu overexpression on chemotherapeutic drug sensitivity in human breast and ovarian cancer cells" <i>Oncogene</i> 15:537-547 (1997)	
	50	PLUTA et al., "Synthesis and biological properties of 4-hydroxy, 4-thio-5-pyrimidine derivatives" <i>Boll. Chim. Farm.</i> 138(1):30-33 (1999)	
	51	RAMU et al. "Circumvention of Adriamycin Resistance by Dipyridamole Analogues: A structure-activity relationship Study" <i>Int. J. Cancer</i> (1989) 43 :487-491	
	52	ROMAIN et al. "Prognostic value of cytosolic thymidine kinase activity as a marker of proliferation in breast cancer" <i>Int. J. Cancer</i> 61:7-12 (1995)	
	53	ROTH et al. "p53 tumor suppressor gene therapy for cancer" <i>Oncology</i> 13(10)(5):148-154 (1999)	
	54	SABOULARD et al. "Characterization of the activation pathway of phosphoramidate triester prodrugs of stavudine and zidovudine" <i>Mol. Pharmacol.</i> 56:693-704 (1999)	
	55	SUKI et al. "Risk classification for large cell lymphoma using lactate dehydrogenase, beta-2 microglobulin, and thymidine kinase" <i>Leukemia and Lymphoma</i> 18:87-92 (1995)	
	56	TEH et al. "Tumor suppressor genes (TSG)" <i>Anticancer Research</i> 19:4715-4728 (1999)	

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	57	van LAAR et al. "Comparision of 5-fluoro-2'-deoxyuridine with 5-fluorouracil and their role in the treatment of colorectal cancer" <i>European J. Cancer</i> (1998) 34(3):296-306	
	58	WALLIS et al. "Synthesis and anit-HIV activity of C4-modified pyrimidine nucleosides" <i>Il Farmaco</i> 54:83-89 (1999)	
	59	ZEID et al. "Synthesis of new thiolated acyclonucleosides with potential anti-HBV activity" <i>Nucleosides & Nucleotides</i> 18(1):95-111 (1999)	

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